



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,664	02/03/2006	Gisela G Chiang	13751-036US1/A167 US	7404
26168	7590	06/30/2009	EXAMINER	
FISH & RICHARDSON			YU, MISOOK	
P.O. BOX 1022			ART UNIT	
MINNEAPOLIS, MN 55440-1022			PAPER NUMBER	
			1642	
			NOTIFICATION DATE	
			DELIVERY MODE	
			06/30/2009	
			ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/519,664	<b>Applicant(s)</b> CHIANG ET AL.	
	<b>Examiner</b> MISOOK YU	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,6-11,14-16,18,20 and 25-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6-11,14-16,18,20 and 25-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/08/09, 04/06/09</u> .                                      | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1, 6-11, 14-16, 18, 20, 25-38 are pending and under consideration.

#### ***Claim Rejections - 35 USC § 102, Maintained***

Claims 1, 9, 10, 11, 18, 20, and 28-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Mastrangelo et al (IDS AP filed on 10/22/2007) Biotechnology and bioengineering vol. 67, pages 544-554 .

Claims 1, 9, 10, 11, 18, 20, and 28-38 are drawn to Bcl-XI over-expressing CHO cells comprising an expressing vector encoding a secreted protein, wherein the CHO cell does not express a heterologous cyclin-dependent kinase inhibitor, and a method of producing the secreted protein.

Applicant argues that the cells taught by Mastrangelo et al., are transients cell line while the instantly claimed invention is a stable cell line.

These arguments have been fully considered but found unpersuasive because Mastrangelo et al., teaches on page 556, right column under the heading "Cell Cultures" Bcl-XI over-expressing CHO cells are stable cell line cells.

#### ***Claim Rejections - 35 USC § 103, Maintained***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 7, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrangelo et al (cited above) in view of Sinacore et al., Biotechnology and bioengineering , 1996, vol. 52, no4, pp. 518-528.

Claims 6, 7, 25 and 26 are drawn to the CHO cells of the respective base claims adapted for growth in suspension in a medium free of serum.

Applicant argues since Mastrangelo et al., does not teach the claimed stable cell line, this rejection should be withdrawn.

This argument has been fully considered but found unpersuasive because Mastrangelo et al., teaches stable cell line as stated above.

Claims 14-16 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrangelo et al (cited above) in view of Kim et al (IDS filed on 10/22/2007, Biotechno Bioeng 71, 184-193).

Claims 14-16 and 32-34 are drawn to Bcl-XL over-expressing CHO cells comprising an expressing vector encoding an antibody.

Applicant argues since Mastrangelo et al., does not teach the claimed stable cell line, this rejection should be withdrawn.

This argument has been fully considered but found unpersuasive because Mastrangelo et al., teaches stable cell line as stated above.

Claims 8 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mastrangelo et al (cited above) as applied to claims 1, 718, 26 in view of Sinacore et al (cited above) and in further in view of Kim et al (cited above)

Claims 8 and 27 are drawn to CHO cell adapted for growth in a serum free medium comprising butyrate.

Applicant argues since Mastrangelo et al., does not teach the claimed stable cell line, this rejection should be withdrawn.

This argument has been fully considered but found unpersuasive because Mastrangelo et al., teaches stable cell line as stated above.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1642

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU  
Primary Examiner  
Art Unit 1642

/MISOOK YU/  
Primary Examiner, Art Unit 1642